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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,045	01/11/2005	Daniel Rachlin	336-1102US	6611
23429 7590 08/06/2008 GREGORY SMITH & ASSOCIATES 3900 NEWPARK MALL ROAD, 3RD FLOOR NEWARK, CA 94560			EXAMINER BOR, HELENE CATHERINE	
			ART UNIT	PAPER NUMBER
			3768	
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			08/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/521,045

Applicant(s)

RACHLIN ET AL.

Examiner

HELENE BOR

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-19 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/02/2008 has been entered.

Claim Rejections - 35 USC § 103

3. Claim 1, 4, 6, 9, 12 & 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paton et al. (US Patent No. 4,120,291), and further in view of Hayakawa et al. (US Patent No. 5,575, 291).

Claim 1, 4, 6, 9 12 & 19: Paton teaches an ultrasound imaging system (Figure 1, Element 1) having a scan head (Figure 1, Element 4) with at least one transducer (Figure 1, Element 6). Paton teaches the interface device being removable to the scan head (Col. 2, Line 40). Paton teaches a reservoir (Figure 1, Element F) with a proximal end and a distal end. Paton teaches where the reservoir is configured to maintain a fluid tight seal between the reservoir and the scan head [sealingly secured] (Col. 2, Line 46-47 & Figure 1, Element 7). Paton teaches a scan window (Figure 1, Element 16) located proximate the distal end of the reservoir through which ultrasound energy is

transmitted and received (Col. 2, Line 43-44). Paton teaches a fluid tight seal (Figure 1, Element 7) between the scan window and the distal of the reservoir and a fluid acoustic coupling membrane located within the reservoir and filling a space between the transducer and the scan window (Figure 1, Element 7). Paton teaches wherein the transducer is allowed to transverse across an intended scan path with the reservoir (Col 3, Line 3-10). Paton fails to teach the membrane being made of solid, non-flowable hydrogel, however, Hayakawa teaches cross-linked [by freezing] hydrogel [hydrated] with greater than 50% water content (Col. 5, Line 28-42) with less than 1dB/cm/MHz (Col. 1, Line 57-59) with a mesh support structure (Figure 3A, Element 60a) and polyethylene oxide (Col. 1, Line 43-44) for ensuring an accurate diagnosis (Col 4, Line 1-4). It would have been obvious to one of ordinary skill in the art to modify the system of Paton to include the features of Hayakawa in order to ensure accurate diagnosing (Col. 4, Line 1-4).

Claim 9: Paton teaches means for adjusting a distance between said scan window and the transducer to allow adjustment of a position of the scan window with respect to a focus of the transducer (Figure 1, Element 53 & 6 & Col. 1, Line 11-18).

Claim 11: Paton fails to teach a shaped scan window, however, Hayakawa teaches fitting the scan window to fit the profile of a body surface even with steep undulations (Col. 4, Line 1-4). Although Hayakawa does not specifically teach the scan window being contoured for the eye, the device is disclosed within Hayakawa as being capable of such a configuration for ensuring an accurate diagnosis (Col. 4, Line 3-4) and it would have been obvious to one of ordinary skill in the art to modify the system of Paton to

include the body contouring of a desired part [an eye] as taught by Hayakawa for ensuring an accurate diagnosis (Col. 4, Line 3-4).

Claim 12: Paton teaches wherein the reservoir comprises a plurality of separate pieces between which the scan window is mechanically secured (Col. 3, Line 1-2).

4. Claim 2, 15 & 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paton et al. (US Patent No. 4,120,291), and in view of Hayakawa et al. (US Patent No. 5,575, 291) as applied to claim 1, 4, 6, 9, 12 & 19 above, and further in view of Katsumata (US Patent No. 5,078,149).

Claim 2, 15 & 18: Paton and Hayakawa fail to teach sterilizing the interfacing device however, Katsumata teaches the interface device being sterile (Col. 5, Line 47-53) for use in surgical operations which require sterilization (Col. 5, Line 50-53). It would have been obvious to one of ordinary skill in the art to modify the system of Paton and Hayakawa to include the sterilization as taught by Katsumata for use in surgical operations which require sterilization (Col. 5, Line 50-53)

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paton et al. (US Patent No. 4,120,291, and further in view of Hayakawa et al. (US Patent No. 5,575, 291) as applied to Claim 1, 4, 6, 9, 12 & 19 above and further in view of Matthews (US Patent No. 3,939,123).

Claim 8: Paton fails to teach hydrogels and Hayakawa fails to teach the specific hydrogel composition. However Matthews teaches hydrogel formed from polyisocyanate terminated poly(alkylene ether) polyols (Col. 2, Line 13-49). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify

the system of Paton and Hayakawa to include the hydrogel composition as taught by Matthews in order to produce a hydrogel with high water absorbency (Col. 5, Line 1-6) because high water content reduces attenuation (Hayakawa; Col. 1, Line 57-59).

6. Claim 10 & 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paton et al. (US Patent No. 4,120,291, and further in view of Hayakawa et al. (US Patent No. 5,575, 291) as applied to Claim 1, 4, 6, 9, 12 & 19 above and further in view of Puech (US Patent No. 6,837,855 B1).

Claim 10: Paton and Hayakawa fail to teach the focus range of the device. However, Puech teaches a device wherein the transducer focus is in the range of 2 to 6 mm past the distal the edge of the device (Col. 6, Line 38-48) in order for specific exploration of the anterior segment of the eye (Col. 6, Line 38). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the system of Paton and Hayakawa to include the transducer focus range as taught by Puech in order for specific exploration of the anterior segment of the eye (Col. 6, Line 38).

Claim 14: Paton and Hayakawa fail fails to teach wherein the ultrasound frequency is in the range of 50 to 100 MHz (Col. 4, Line 41-50 & Col. 6, Line 38-48) in order to have better image resolution (Col. 2, Line 15-18). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the system of Paton and Hayakawa to include the frequency range as taught by Puech in order to have better image resolution (Col. 2, Line 15-18) for specific exploration of the anterior segment of the eye (Col. 6, Line 38).

7. Claim 16 & 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paton et al. (US Patent No. 4,120,291, and further in view of Hayakawa et al. (US Patent No. 5,575, 291) as applied to Claim 1, 4, 6, 9, 12 & 19 above and further in view of de Juan et al. (US Patent Application No. 2001/0029335 A1).

Claim 16: Paton and Hayakawa fails to teach the surgical instrument. However, de Juan'335 teaches the device incorporating a surgical instrument (Figure 5A, Element 305a & 206, Figure 6A & 6B and Page 4, Paragraph 0042). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to combine the teachings of Paton and Hayakawa and de Juan in order for a surgeon to scan the retina during the procedure to evaluate the effectiveness of the action taken (Page 4, Paragraph 0046).

Claim 17: Paton and Hayakawa fails to teach the surgical instrument. However, de Juan teaches the device wherein the device incorporates a surgical instrument that allows use of the instrument in positional relationship to the scanned image (Page 1, Paragraph 0010). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to combine the teachings of Paton and Hayakawa and de Juan in order to better plan the surgical approach and provide high resolution images.

Allowable Subject Matter

8. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

9. Applicant's arguments, see Page 5, filed 07/02/2008, with respect to 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. The 35 U.S.C. 112, second paragraph rejection of 1-18 has been withdrawn.
10. Applicant's arguments with respect to claim 1-18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELENE BOR whose telephone number is (571)272-2947. The examiner can normally be reached on M-T 8:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. B./
Examiner, Art Unit 3768

/Eric F Winakur/
Primary Examiner, Art Unit 3768